Author's response to reviews

Title: Factors influencing the participation of gastroenterologists and hepatologists in clinical research

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Author's response to reviews: see over
To the Editors:

My colleagues and I are pleased to submit our revised manuscript entitled “Factors Influencing the Participation of Gastroenterologists and Hepatologists in Clinical Research” to BMC Health Services Research.

We are grateful for the opportunity to make additional revisions to our manuscript in response to Reviewer 3’s comments. Accompanying this cover letter is our point-by-point response to the comments.

I will continue to serve as the corresponding author. Please do not hesitate to contact me by e-mail at mchut001@mc.duke.edu if you have any questions.

Sincerely,

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Responses to Reviewer: Merran Toerien

1. The authors have, appropriately, added a statement about why they compared gastroenterologists and hepatologists. However, I was also hoping that they would provide some explanation for choosing this field of medicine rather than another as a focus for their study. I think that they allude to a reason on p. 11 (Discussion): “given the paucity of related research in other specialties and the limitations of existing studies, definitive conclusions about barriers to clinical trial participation across specialties are difficult to make”. It would be helpful if the authors could add a sentence to the introduction or the methods section stating something along these lines – i.e. that although there is prior research on reasons for trial participation, but this has been limited with regard to range of specialties–hence this study.

Informal discussions between the authors and colleagues in gastroenterology and hepatology suggested that some physicians who were interested in clinical research were unable to participate in such studies and that there were differences in practice preferences between gastroenterologists and hepatologists. Upon further investigation, we determined that, although there was a fair amount of work investigating oncologists’ roles in clinical research, there had been little such analysis outside oncology (internal medicine being the chief exception) and no formal investigation within gastroenterology. Those observations prompted the current study.

We have added a statement at the beginning of the Discussion to highlight the fact that the bulk of prior research in this area has focused on oncology, internal medicine, and general practice.

6. Limitations. The sentence in which the authors have addressed my point is worded confusingly:

“We targeted members of the AASLD under the assumption that most gastroenterologists and hepatologists with an interest in clinical research likely would be associated with the organization. To the extent that this assumption may be incorrect, our findings may not be representative of all gastroenterologists and hepatologists eligible to conduct clinical research in the United States, particularly those who may perceive high barriers to participation in such activities” (p.13).

It is true to say that if their assumption is incorrect they may have a sample which is not representative of those eligible to conduct clinical research in the US. However, the latter point – that they may have missed those physicians who are less likely to take part in research – is a problem if their assumption is correct (!) because they are, potentially, tapping those physicians most likely to be research active. These sources of bias should be discussed separately, not in a single sentence.

We have rewritten this paragraph to better describe the two sources of bias: first, that AASLD members may not be representative of all gastroenterologists and hepatologists interested in conducting clinical research; second, that we will have excluded those facing the highest barriers to participation. The latter problem suggests that we will have underestimated barriers to clinical research participation among US gastroenterologists and hepatologists.

7. Figures. Unfortunately, I no longer have a copy of the original set of tables included by the authors. However, it seems to me that their decision to remove some of them was detrimental to the paper, rather than an improvement. In particular, I felt that there should at least be a table showing barriers to participation (i.e. a mirror of the current Table 3 – factors influencing participation in clinical trials). I also felt that the authors’ removal of the subheadings in the results section made it less clear, rather than more so.
The results to the barriers question (Question 16) were presented within the text in both the original and revised versions. In response to comments from another reviewer, we included additional comparisons between gastroenterologists and hepatologists and between clinical researchers and non-researchers. Rather than add a new set of tables and figures for these comparisons, we opted to consolidate some tables and convert several figures to table format. Unfortunately, we missed the opportunity to consolidate the barrier results in the same way. It makes sense, as the reviewer notes, to include a table analogous to Table 3 with the results of the barriers question. We appreciate the reviewer’s comment to correct this oversight. This information now appears as Table 4, with the prior Table 4 now appearing as Table 5.

We have eliminated the subheadings in response to another reviewer’s comment. Although subheadings may allow readers to identify results of greatest interest to them, other readers may find them distracting. We are happy to add them but will defer to the editors in making the final decision.

8. I thought the Discussion was much improved. However, I would ask the authors to add a sentence or two clarifying what they mean by “their responses may reflect the realities of conducting research in the current climate” (p.12).

We have elaborated on this statement, as requested.

Also, with respect to the final paragraph on p.12 (“Another possible explanation...”): could the authors clarify whether their claims here about exposure are based on their personal knowledge of the field or if there is any published evidence supporting the contrast they describe.

This statement came from the authors’ personal experience and discussions with colleagues which led to the current study (see also response to comment 1, above). We are not aware of any published evidence documenting this observation. A clause has been added to the beginning of the statement mentioned above to emphasize that this is the authors’ own observation.

Minor typo
p.12.
“In the United States, reimbursement for many medical procedures has been relatively higher—on an hourly basis—than for evaluation and management services [16,17], thought that gap has been reduced by changes in the Medicare fee schedule over time [18]”. “thought that gap” should be “though that gap”.

Thank you for catching this typo; it has been corrected.